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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,139	01/28/2004	Stefan Schreck	ECV-5541DIVCON	1979

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EDWARDS LIFESCIENCES CORPORATION
LEGAL DEPARTMENT
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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,139

Applicant(s)

STEFEN SCHRECK

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-22, 24-26 and 38-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22, 24-26, and 38-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 18-28 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 42, 43, 45, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "tissue-engaging base portion" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to delete --portion--.

Claim 42 recites the limitation "the outflow end" in both lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change the above to recite --the outflow end of the tissue-engaging base--.

Claim 43 recites the limitation "each pair of the mating connectors" in line 1. There is insufficient antecedent basis for this limitation in the claim. A plurality of connectors has been claimed, however, not pairs of connectors.

Claim 45 recites the limitation "tissue-engaging base portion" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to delete --portion--.

Claim 49 recites the limitation "the mechanical coupling members" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "mechanical" to recite --metallic--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38-41 and 44-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Thorpe et al. (US 2003/0130726 A1). Thorpe discloses a two part prosthetic heart valve (see figs.14-16) comprising an expandable tissue-engaging base (bottom stage stent in figs.14-16), a leaflet subassembly (top stage stent+valve in figs.14-16) comprising a support (stent 137 of top stage) and three heart valve leaflets (146; 3 leaflets 89 shown in fig.13 for example) attached at commissures (see attachments 91 in fig.13), and a plurality of discrete mating connectors made of metal (connectors considered to be eyelets on each stage which wire 140 is shown connecting adjacent eyelets), on the leaflet subassembly and the tissue-engaging base adapted to mechanically couple together (see fig.14). Thorpe discloses the leaflets (146 or 89) to be axially spaced from the outflow end of the tubular body of the tissue-engaging base (leaflets on top stage are spaced from bottom stage in figs.14-16). Thorpe discloses the metallic couple members on the base to comprise axial posts (a connector may be considered one strut of bottom stage stent, 137) adapted to couple to couple members on the leaflet subassembly (fig.14).

Claims 18, 19, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Cribier (US 6,908,481 B2). Cribier discloses a two part prosthetic heart valve (see figs.14-15 and respective portions of the specification) comprising a substantially cylindrical tissue-engaging base (10) that is expandable and a leaflet subassembly (10') including a metallic support structure (stent frame 11 of 10') and three valve leaflets (see three leaflets shown in detail in fig.4b) attached to the support at commissures (along line 20, seen in detail in fig.7), the support having a fabric covering (19), the leaflets attached to the support (stent 11) by stitches along the fabric covering (along line 20, see fig.6, 7), the leaflet subassembly configured to mechanically connect to the base (fig.15). Cribier discloses leaflets that are bioprosthetic tissue (col.15, lines 6-9) and wherein the base is plastically expandable (col.9, lines 14-22).

Claims 18-22, 24-26, and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Eberhardt (US 6,350,282, previously cited). Eberhardt discloses a two part prosthetic heart valve comprising a substantially cylindrical tissue-engaging base (54 or 46 alone) that is expandable (46 is disclosed to be made of felt, a inherently flexible material, capable of being folded or compresses to a smaller diameter; col.5, line 6; see also col.5, lines 27-46) and a leaflet subassembly including a metallic support structure (36) and three valve leaflets (26, 28, 30) attached to the support at commissures (fig.6, 7), the support having a fabric covering (48), the leaflets attached to the support (36) by stitches (56) along the fabric covering, the leaflet subassembly configured to mechanically connect to the base (fig.4). Eberhardt discloses leaflets that are bioprosthetic tissue (col.4, lines 28-37) and wherein the base (46) is plastically expandable (plastically expandable when expanded past it's shape) or self-expanding (self expanding when folded/unfolded).

Claims 38-41 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916, cited previously). Garrison discloses a two part prosthetic heart valve (see figs.34-38 for one perspective and figs.8-10 for another perspective) comprising an expandable tissue-engaging base (8D or 8), a leaflet subassembly (6D or 6) comprising a support (26D+111 or 26) and three heart valve leaflets (38; see fig. 11, 34, 38) attached at commissures (in figs.34-38, fold of tube valve attaches at kinks 106 in support; commissure considered to be a joining place or line; or near 32 in figs.8-10), and a plurality of discrete mating connectors (34D and 108 seen in figs.34-38; OR protrusions 34 and openings 14 seen in figs.8-10; col.5, lines 29-35) on the leaflet subassembly (34D or 34) and the tissue-engaging base (108 or 14) adapted to mechanically couple together.

Allowable Subject Matter

Claim 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER